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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,198	07/20/2001	Steven P. Sidwell	2758	1473

7590

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,198

Applicant(s)

SIDWELL ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 21 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper dated 10/20/2003.

This application contains claims drawn to an invention nonelected with traverse in Paper dated 10/20/2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 8-13 and 16-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by May (EP 0,291,194) in light of Scientific Products Catalog.

May teaches an assay device comprising a hollow casing constructed of moisture-impervius solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device containing a labeled specific binding reagent for an analyte which labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte which unlabeled reagent is permanently immobilized in a detection zone on the carrier material (page 3). The device also contains a control zone loaded with an antibody that will bind to the labeled antibody from the

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first zone. The control zone can contain an anhydrous reagent that when moistened, produces a color change or color formation. May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (page 10). May teaches backing the porous nitrocellulose sheet with plastic to increase handling strength (page 13). May teaches the use of Schleicher & Schuell paper which is disclosed by the Scientific Products Catalog as pure white paper.

Even though May is silent on a "means for providing a complimentary color background", May is seen to anticipate the claims for two reasons: (1) "complimentary" has not been properly defined, and (2) white is a color that can be seen as "complimentary color background".

4. Claims 1, 2, 8, 9, 12, 13, 16 and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chandler (US 5,877,028).

Chandler discloses a chromatographic assay device for use with immunoassays. The device comprises: (1) a first opposable component comprising a sample preparation zone adapted to receive a sample to be assayed; and (2) a second opposable component comprising a chromatographic medium. The first and second opposable components can be brought into opposition so as to cause the sample preparation zone to apply the sample to be tested to the chromatographic medium. Preferably, the analyte is detected with a visually detectable label. See column 18. Chandler teaches that the applicator 352 (sample application pad) preferably comprises an inert dye so that the flow of the sample through the chromatographic medium can be monitored visually. Preferably, the inert dye is of a contrasting color to that of the detectable label. For example, when the detectable label is pink colloidal gold, the inert dye can be blue. See column 34, lines 40-64.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6, 7, 14, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over May or Chandler each in view of Ogawa et al (US 4,303,409).

See the discussion of May and Chandler above. These references differ from the instant invention in failing to teach a test strip with specific color.

Ogawa discloses a test strip for colorimetric analysis of ascorbic acid in a liquid sample. Ogawa teaches a dye for adjusting background color such as food dyes of yellow No. 4 or blue No. 1 or an appropriate copper salt may be employed in the test strip for clarity and sensitivity of the detection. See column 3, lines 33-37.

Even though these references do not specifically disclose a blue or red label for use with a yellow or green background, respectively, such a color scheme is not novel and is deemed to be in the purview of the manufacturer. A skilled artisan would have had a reasonable expectation of success in modifying the test paper taught by May and Chandler by incorporating a background color for added visual perception of the result as taught by Ogawa.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. – 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'B. Nguyen', with a long horizontal flourish extending to the right.

Bao-Thuy Nguyen
Primary Examiner
18 December 2003